

REMARKS

**Status of the Claims**

Claims 1, 2 and 4-36 are currently pending in the application. Claims 1-34 stand rejected. Claims 35 and 36 are withdrawn as being drawn to a non-elected invention. Claims 1, 2 and 10 have been amended as set forth herein. Claim 3 has been cancelled. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendment to claim 1 is supported by the subject matter of claim 3, now cancelled. Claim 2 has been amended to remove the phrase, "a surface-active agent" which is now recited in independent claim 1. Claim 10 has been amended to change its dependency to claim 1 from cancelled claim 3. Reconsideration is respectfully requested.

**Unity of Invention**

The Examiner states that the present application discloses more than one invention under the unity of invention standard according to PCT Rule 13.1. (*See*, Office Action of May 16, 2007, at page 3, hereinafter, "Office Action"). The Examiner has required election of one of the inventions of Groups I-III. Applicants affirm the election, with traverse, of the invention of Group I, drawn to method claims 1-34 for further prosecution.

According to MPEP § 803, if the search and examination of an entire application can be made without a serious burden, the Examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions. Applicants submit that it would not be an undue burden to search a reagent kit and apparatus depending from claims within the elected

group. Furthermore, Applicants do not agree that Muller et al., U.S. Patent No. 6,084,091 (hereinafter, "Muller et al.") discloses the "special technical feature of the presently claimed invention.

Therefore, reconsideration and withdrawal of the restriction requirement of claims 1, 2 and 4-36 are respectfully requested.

### **Priority**

The Examiner alleges that Applicants cannot claim priority to applications filed in Japan in 2003 and 2004. (*Id.* at page 3). The Examiner is obviously mistaken. As is clearly apparent from the original papers filed February 13, 2006 and acknowledged by the USPTO Notice of Acceptance of October 4, 2006, the effective U.S. filing date of the present application is September 8, 2004, the filing date of the International Application PCT/JP04/13384. The Examiner has not provided (and clearly cannot provide) any reasons why this filing date is not the effective U.S. filing date. (See, 35 U.S.C. §§ 363 and 365, as well as MPEP §§ 201.13(b) and 1828). All of the Japanese foreign priority applications to which the present application claims priority were filed within one year of the effective filing date. Furthermore, the present U.S. National Stage application was filed within 30 months of the earliest filing date of the Japanese foreign priority applications.

Correction and/or retraction of the Examiner's statements concerning priority is respectfully requested.

### Information Disclosure Statement

The Examiner states that the foreign patent documents cited on the form 1449 were not considered because no translation thereof was received by the USPTO. (*Id.*). The Examiner is again mistaken. First, Examiner should at least consider the cited U.S. applications and return the dated and initialed form SB08. Furthermore, the Information Disclosure Statement of February 13, 2006, at page 3, clearly provides the following relationship between the three U.S. cited references and three of the cited Japanese patent applications (*emphasis added*):

A concise explanation of relevance of the items listed on form PTO/SB/08 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references. Furthermore, U.S. Patent Publication 2003/0170664 corresponds to JP-A-2003-128691; U.S. Patent Publication 2002/0192667 corresponds to JP-A-2002-360245; and U.S. Patent 5,643,721 corresponds to JP-A-9-508532.

Again, at least these three Japanese applications should have been considered and acknowledged as corresponding to the above-mentioned U.S. patents and published applications. The Examiner is respectfully reminded that under the current Rules, Applicants need not submit U.S. Patent documents or publications to the USPTO for consideration. (See, 37 CFR 1.98(a)(2)(i), amended October 2004, the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications).

Furthermore, the only references remaining to be considered without English language abstracts are JP-2003-144150 and JP-2003-506456. However, Applicants submitted with the IDS an English language translation of the International Search Report listing these references and providing the relevance of these references. No more is required of Applicants under the

Rules concerning IDS submissions. The Examiner is respectfully invited to review 37 C.F.R. § 1.98(a)(3) *et seq.* for the current Rules concerning such IDS submissions. Especially see MPEP § 609.04(a)(III), page 600-153 (Rev. 5, August 2000) which expressly states that a translation is not required.

The Examiner is respectfully requested to again review the IDS of February 13, 2006 and sign and return the initialed form SB08 submitted therewith. Applicants have complied with all of the Rules for such submissions under 37 C.F.R. § 1.98.

#### **Rejections Under 35 U.S.C. § 102(b)**

##### **Woodard, U.S. Patent No. 5,405,951**

Claims 1-3, 8, 10, 11, 23, 27, 30, 33 and 34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Woodard, U.S. Patent No. 5,405,951 (hereinafter, "Woodard"). (See, Office Action, at page 4). Claim 3 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to this claim. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that Woodard discloses all the limitations of the cited claims. For instance, regarding claim 1 and the disclosure of Woodard, the Examiner equates alcohols such as PEG and glycerol with antifoaming agents, as recited in part (3) of claim 1.

Although Applicants do not agree that the presently claimed invention is anticipated by the disclosure of Woodard, to expedite prosecution, claim 1 has been amended herein without prejudice or disclaimer to recite, in part, "wherein the sample solution containing nucleic acid is prepared by further addition and mixing of a pretreatment solution containing an antifoaming

agent and a surface-active agent, and wherein the sample solution containing nucleic acid is prepared by further addition of a water-soluble organic solvent."

The polyethylene glycol (PEG) in Woodard that the Examiner relies on as the disclosure of an antifoaming agent, is cited by the Examiner as being an equivalent of the water-soluble organic solvent of the present invention. However, there is no disclosure in Woodard that an antifoaming agent is added separately from a compound which functions as a water-soluble organic solvent.

With respect to Woodard, the disclosure of Woodard is not related to the methods of the presently claimed invention, the purpose of which is to isolate and purify a nucleic acid, because the PEG disclosed in Woodard does not retain a nucleic acid onto a solid phase. Thus, Woodard does not achieve the goal of isolating and purifying a nucleic acid. The table described in column 7 of Woodard compares the ability to retain a nucleic acid onto a solid phase of the binding buffer used in the working examples, such as a water-soluble organic solvent and a chaotropic salt. The table indicates that the embodiment comprising PEG addition cannot retain a nucleic acid onto a solid phase. Therefore, according to the teaching of Woodard, the addition of PEG is not suitable for a method for isolating and purifying a nucleic acid.

Dependent claims 2, 8, 10, 11, 23, 27, 30, 33 and 34 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, amended claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1, 2, 8, 10, 11, 23, 27, 30, 33 and 34 are respectfully requested.

Su, WO 97/08547

Claims 1-3, 8-13 and 19-28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Su, WO 97/08547 (hereinafter, "Su"). (*See*, Office Action, at page 6). Claim 3 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to this claim. Applicants traverse the rejection as to the remaining claims as set forth herein.

Regarding the disclosure of Su, the Examiner makes similar assumptions and statements as made above with respect to Woodard, pointing to Example 1 and pages 7-12 and 25 of the disclosure of Su for support of the rejection.

As in Woodard, the PEG disclosed in Su that the Examiner relies on as the disclosure of an antifoaming agent is cited as an equivalent of the water-soluble organic solvent of the present invention. Again, as in Woodard, there is no disclosure in Su that an antifoaming agent and a compound functioning as a water-soluble organic solvent are added separately.

Although Applicants do not agree that the presently claimed invention is anticipated by the disclosure of Su, to expedite prosecution, claim 1 has been amended herein without prejudice or disclaimer to recite the limitations of claim 3. Applicants believe this amendment fully addresses the Examiner's concerns for the reasons provided herein.

Dependent claims 2, 8-13 and 19-28 are not anticipated as, *inter alia*, depending from a non-anticipated basic claim, amended claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 2, 8-13 and 19-28 are respectfully requested.

**Rejections Under 35 U.S.C. § 102(a)**

Claims 1-4, 9-24 and 26-34 stand rejected under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e) as being anticipated by Iwaki, U.S. Patent Application Publication No. 2005/0112656 (hereinafter, “Iwaki”). (*See*, Office Action, at page 8). Claim 3 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to this claim. Applicants traverse the rejection as to the remaining claims as set forth herein.

Iwaki is not prior art. The U.S. filing date, e.g. International Application filing date, of the present application is September 8, 2004, which is before the filing date of Iwaki and before the publication date of Iwaki. (*See*, 35 U.S.C. § 363).

Reconsideration and withdrawal of the anticipation rejection of claims 1, 2, 4, 9-24 and 26-34 are respectfully requested.

**Rejections Under 35 U.S.C. § 102(e)**

Claims 1-4, 9-24 and 26-34 stand rejected under 35 U.S.C. § 102(c) and 35 U.S.C. § 102(e) as being anticipated by Iwaki, U.S. Patent Application Publication No. 2005/0112656 (hereinafter, “Iwaki”). (*See*, Office Action, at page 8). Claim 3 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to this claim. Applicants traverse the rejection as to the remaining claims as set forth herein.

Iwaki is not prior art. The U.S. filing date, e.g. International Application filing date, of the present application is September 8, 2004, which is before the filing date of Iwaki and before the publication date of Iwaki. (*See*, 35 U.S.C. § 363).

Reconsideration and withdrawal of the anticipation rejection of claims 1, 2, 4, 9-24 and 26-34 are respectfully requested.

**Rejections Under 35 U.S.C. § 103(a)**

Claims 1, 2 and 4-9 stand rejected under 35 U.S.C. § 103(a) for being unpatentable as obvious over Woodard in light of Su and Kappel et al., U.S. Patent Application Publication No. 2004/0259162 (hereinafter, “Kappel et al.”) and Sigma Data Sheet. (See, Office Action, at pages 13-15). Applicants traverse the rejection.

The Examiner states that Woodard and Su do not disclose or suggest the limitation of an antifoaming agent being a silicon-type antifoaming agent, as recited in claim 4. However, the Examiner cites to the disclosure of Kappel et al. to find disclosure of this missing limitation. Thus, the Examiner concludes that it would have been obvious to combine this disclosure of Kappel et al. with the disclosures of Woodard and Su to achieve the methods of the presently claimed invention.

In addition to the remarks provided above with respect to the anticipation rejection in view of Woodard and Su, Applicants also believe that Woodard teaches away from any combination with the disclosures of Su or Kappel et al. That is, concerning the disclosure of Woodard, the use of PEG precludes the ability to retain a nucleic acid onto a solid phase. That is, referring to column 7 of Woodard, the ability to retain a nucleic acid on a solid phase depending on the identity of the binding buffer used in the working examples is disclosed. In this column, Woodard clearly shows that embodiments containing PEG cannot retain a nucleic acid on the solid phase. That is, Woodard discloses that addition of PEG to a binding buffer is

not recommended. Therefore, there is no motivation to combine the disclosure of Woodard with any of the other cited references because doing so would yield an embodiment that does not work. Such a combination of disclosures cannot be made because Woodard teaches away from use of PEG. Thus, one of ordinary skill in the art cannot combine the disclosure of Woodard with any other reference to make obvious the presently claimed invention.

While patents or references are relevant as prior art for all they contain, they cannot be relied upon to teach embodiments that are not reasonably suggested to one having ordinary skill in the art. (*See, Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804 (Fed. Cir. 1989)). In this regard, such hypothetical embodiments are being generated here to achieve the present invention when the Examiner is taking only pieces of each reference and disregarding other essential disclosures of the references. Thus, the cited references are relevant as prior art for all they contain but at the same time cannot be relied upon to teach embodiments that are not reasonably suggested to one having ordinary skill in the art. (*See, Merck & Co.; supra*). In this case, Woodard clearly discloses that a binding buffer containing PEG is inoperative. Yet, the Examiner states that Woodard should be combined with other disclosures inconsistent with this teaching.

Furthermore, Su discloses or suggests a solid phase “without an effective positive charge.” (*See, Su at example on page 3*). In contrast, Kappel et al. disclose the use of a “positive charge” on an adsorbing group (solid phase). Thus, even the combination of Su with Kappel et al. is inappropriate since these disclosures recommend opposite embodiments. It is doubtful one of ordinary skill in the art would thus combine these three disclosures. Even if, *arguendo*, one of skill in the art did merge all three disclosures, the suggested embodiments would be so numerous

and so inconsistent with each other that it is difficult to say which might work and which might not. There would be no way to predict any possible outcome of success.

In this regard, a claimed combination cannot change the principle of operation of the primary reference or render a reference inoperable for its intended purpose. (See, M.P.E.P. §§ 2143.01, sections entitled “The Proposed Modification Cannot Render the Prior Art Unsatisfactory For Its Intended Purpose” and “The Proposed Modification Cannot Change the Principle of Operation of a Reference,” and M.P.E.P. § 2145(III)). The Federal Circuit has also held: “If references taken in combination would produce a ‘seemingly inoperative device,’ we have held that such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness.” (See, *McGinley v. Franklin Sports Inc.*, 60 U.S.P.Q.2d 1001, 1010 (CAFC 2001), citing *In re Sponnoble*, 405 F.2d 578, 587, 160 U.S.P.Q. 237, 244 (CCPA 1969), holding that references teach away from combination if combination produces seemingly inoperative device; and *In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984), finding that an inoperable modification teaches away). Here, the Examiner’s combination mixes together disclosures that are incompatible and teach away from each other. The disclosures cannot be combined because they teach embodiments that are inconsistent with each other.

In addition to the arguments presented above, Applicants again note that claim 1 has been amended herein without prejudice or disclaimer to recite the limitations of claim 3.

Finally, Applicants insist that the Examiner is using hindsight reconstruction to assemble enough references to support the obviousness rejection. That is, through a process of impermissible hindsight reconstruction, the Examiner is completely reconstructing the teachings

of the references in view of the Applicants' own disclosure. (*See, Grain Processing Corp. v. American Maize-Products Co.*, 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988), stating "Care must be taken to avoid hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit,'" internal citation omitted; and *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), stating "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.").

As recently followed in *Alza Corp.*, the Federal Circuit has consistently held that an Examiner cannot use the claim of the Applicant "as a template . . . selecting elements from references to fill the gaps." (*Alza Corp. v. Mylan Pharma., Inc.*, 2006 U.S. App. LEXIS 22616, \*9, 8 U.S.P.Q.2d 1001 (Fed. Cir. 2006), and *In re Gorman*, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991), *see also, Interconnect Planning Corp. v. Feil et al.*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985), stating, "[t]he claims were used as a frame, and individual naked parts of separate prior art references were employed as a mosaic to recreate a facsimile of the claimed invention."). Such is the case here where the Examiner must dissect bits and pieces of the various references to finally find enough pieces of disclosure to arrange onto Applicants' claims thus allegedly completing a jigsaw-like puzzle in an attempt to establish an obviousness rejection. Further, the Examiner makes such a combination despite disclosures, such as Woodard, that teach away from the combination. Accordingly, reconsideration and withdrawal of the obviousness rejection of claims 1, 2 and 4-9 are respectfully requested.

**Rejections Under the Obviousness-Type Double Patenting Doctrine**

As to all provisional rejections under the judicially created doctrine of obviousness-type double patenting, the Examiner is respectfully requested to follow the procedure that is described in M.P.E.P. § 804(I)(B)(1), and reads as follows:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Accordingly, as to later-filed co-pending applications, the Examiner is respectfully requested to issue a Notice of Allowance in the present application and to address any possible double patenting issues in the later co-pending applications.

Concerning the co-pending applications that are earlier filed, since claim amendments are being made in one or more of these applications which would render the rejection moot, Applicants believe none of the presently pending claims are identical and all are patentably distinct from the cited co-pending applications.

**CONCLUSION**

If the Examiner has any questions or comments, please contact Thomas J. Siepmann,  
Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future  
replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for  
any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of  
time fees.

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Respectfully submitted,

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